IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON PHARMA IRELAND LIMITED, HZNP LIMITED and HORIZON PHARMA USA, INC., *Plaintiffs,* v. ACTAVIS LABORATORIES UT, INC. *Defendant.*	C.A. No. 14-cv-7992-NLH-AMD (Consolidated with C.A. Nos. 15-cv-5025, 15-cv-6131, and 15-cv-6989) Hon. Noel L. Hillman, U.S.D.J. Hon. Ann Marie Donio, U.S.M.J.
HORIZON PHARMA IRELAND LIMITED, HZNP LIMITED and HORIZON PHARMA USA, INC., *Plaintiffs,* v. AMNEAL PHARMACEUTICALS LLC, *Defendant.*	C.A. No. 15-cv-3367-NLH-AMD (Consolidated with 15-cv-5024, 15-cv-6132)) C.A. No. 15-cv-6990-NLH-AMD Hon. Noel L. Hillman, U.S.D.J. Hon. Ann Marie Donio, U.S.M.J. ***Confidential – Document Electronically Filed Under Seal***

DEFENDANTS ACTAVIS LABORATORIES UT, INC. AND AMNEAL PHARMACEUTICALS LLC'S JOINT OPENING *MARKMAN* BRIEF

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

TREATISES

I. INTRODUCTION

Defendants Actavis Laboratories UT, Inc. ("Actavis") and Amneal Pharmacueticals LLC ("Amneal") (collectively, "Defendants") respectfully provide their Joint Opening *Markman* Brief in support of their proposed construction of certain terms of the nine asserted patents-in-suit.

Faced with extremely close prior art and vague claims, Plaintiff Horizon takes the unsual step of asking the Court to narrow Horizon's own patent claims and clarify the disputed terms by improperly adding further limitations to the claims of the patents-in-suit. The precarious validity of Horizon's patents is not a valid reason to permit Horizon to:

- convert "consisting essentially of" into a context-dependent term divorced from any purported "basic and novel properties" of the invention;
- redefine "ethanol" as a specific percentage mixture of ethanol and water;
- arbitrarily reclassify an unidentified "impurity A" as USP Dicofenac Related Compound A RS, a known diclofenac intermediate that is never mentioned in the Horizon patents;
- arbitrarily limit "topical diclofenac preparation" to a gel or solution, contrary to the plain language of the claims and the ordinary meaning of the term.
- graft a requirement that a "medical care worker" instruct a patient that has no basis in the claims.

These are but a few examples of Horizon's improper approach. By contrast, Defendants propose constructions for each disputed term that are consistent with the plain language of the claims. Further, Defendants do not ask the Court to inject language into the claims that is simply not there in an effort to fix indefinite terms.

II. BACKGROUND

A. Topical Diclofenac Sodium

1. Actavis's and Amneal's ANDA Products

These suits concern Actavis's Abbreviated New Drug Application ("ANDA") No. 207238 and Amneal's ANDA No. 208198, each of which pertains to diclofenac sodium topical solution 2% w/w. Diclofenac is a non-steroidal anti-inflammatory drug ("NSAID") that was first synthesized in 1973 and is available in varying concentrations in several topical pain medications, including Voltaren® (1%), Flector® (1.3%), Pennsaid® (1.5% & 2%), and Solaraze® (3%). Horizon alleges that Defendants' ANDA products will infringe nine patents listed in the Orange Book in connection with Pennsaid 2% w/w.

2. Pennsaid®

The FDA has approved two Pennsaid products – Pennsaid 1.5% and Pennsaid 2%. Nuvo Research, Inc. ("Nuvo") developed both products, which differ in the amount of diclofenac sodium they contain. Ex. 1, Nuvo Compl., ¶ 27-28. Nuvo developed Pennsaid 2% with the idea that it "would enjoy market and patent exclusivity once market exclusivity for original Pennsaid [1.5% w/w] expired." *Id.*, ¶¶ 29, 35, 40. After termination of a license of Pennsaid 1.5% w/w to Mallinckrodt, Inc. (*id.*, ¶ 6, 15), Nuvo subsequently assigned to Horizon the New Drug Application and U.S. patents relating to Pennsaid 2%. Dkt. 1, ¶¶ 36-42.

B. The Patents-in-Suit

The patents-in-suit pertain to a diclofenac sodium topical formulation and methods for using such a formulation to treat pain associated with osteoarthritis ("OA") of the knee. Ex. 2,

'838 patent, abstract;[1] Ex. 3, '450 patent, abstract, 4:15-19. The patents-in-suit fall into two patent families – the '838 formulation patent family and '450 method of treatment patent family.

1. '838 Formulation Patent Family

The earliest application in the '838 patent family is U.S. Provisional Application No. 60/829,756, which was filed on October 17, 2006. Horizon currently asserts five members of the '838 patent family against Defendants, including U.S. Patent Nos. 8,252,838 ("'838 patent"); 8,563,613 ("'613 patent"); 8,871,809 ("'809 patent"); 9,066,913 ("'913 patent"); and 9,101,591 ("'591 patent"), which are shaded pink in the family tree attached as Exhibit 4.[2]

a. Asserted Claims of the '838 Patent Family

Virtually all of the asserted claims of the five patents-in-suit in the '838 patent family recite a topical formulation that contains five common ingredients in various percentages by weight: (1) diclofenac sodium (1-5% w/w); (2) dimethyl sulfoxide ("DMSO") (30-60% w/w); (3) ethanol (1-30% w/w); (4) propylene glycol (1-15% w/w); and (5) water.[3] Ex. 4, '838 patent family tree. Various claims include additional limitations requiring: (i) particular percentages of some components within the above-listed ranges; (ii) supplemental ingredients; or (iii) particular properties of the claimed formulations. *E.g.*, Ex. 2, '838 patent, claim 49 (requiring 1-2% diclofenac sodium, 40-50% DMSO, 23-29% ethanol and 10-12% propylene glycol; adding hydroxypropylcelluose as an ingredient; and reciting "a viscosity of 500-5000 centipoise").

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[1] "Ex." refers to the corresponding exhibit attached to the Declaration of Joshua E. Ney in Support of Actavis and Amneal's Joint Opening Markman Brief, filed concurrently herewith.

[2] On October 28, 2015, Horizon also sued both Actavis and Amneal for alleged infringement of recently issued U.S. Patent Nos. 9,168,304 ("'304 patent") and 9,168,305 ("'305 patent"). Defendants reserve the right to brief any additional terms of the '304 and '305 patents requiring construction and have those constructions determined during the scheduled Markman hearing.

[3] Claim 1 of the '809 patent presents the sole exception; claim 1 of the '809 patent does not explicitly recite ethanol, propylene glycol or water. Ex. 5, '809 patent, claim 1.

In the reproduction of claim 49 of the '838 patent below, the common core ingredients of the asserted claims of the '838 patent family are underlined:

> 49. A topical formulation, consisting essentially of:
> 1-2% w/w diclofenac sodium;
> 40-50% w/w DMSO;
> 23-29 % w/w ethanol;
> 10-12% w/w propylene glycol;
> hydroxypropyl cellulose; and
> water to make 100% w/w, wherein the topical formulation has a viscosity of 500-5000 centipoise.

b. Common Specification of the '838 Patent Family

The specification of the '838 patent family members is materially identical.[4] The specification admits that a prior art topical diclofenac sodium composition existed that was "effective in chronic OA treatment." Ex. 2, '838 patent, 1:64-2:1. The '838 patent refers to this prior art composition as the "comparative liquid formulation." *Id.*, 7:28-32.

As shown in the table below, the '838 patent discloses that the prior art comparative liquid formulation contains the same ingredients, largely in the same quantities by percent weight, as required by claim 49 of the '838 patent. As shown, the principal difference between the prior art comparative liquid formulation and the claimed formulation is the addition of the thickening agent, hydroxypropylcellulose, to form a gel.[5]

Component of Claimed Formulation	'838 patent, claim 49	Comparative Liquid Formulation
Diclofenac sodium	1-2%	1.5%
DMSO	40-50%	45.5%

[4] For convenience, Actavis cites only the '838 patent specification throughout this brief. The same language appears in the specifications of the other '838 patent family members.

[5] Thickening agents such as hydroxyproplycellulose were well-known pharmaceutical excipients prior to the alleged invention of the '838 patent.

Component of Claimed Formulation	'838 patent, claim 49	Comparative Liquid Formulation
Ethanol	23-29%	11.79%
Propylene Glycol	10-12%	11.2%
Hydroxypropylcellulose	Required, but no quantity specified	-
Glycerine	-	11.2%
Water	Remainder	Remainder

The majority of the '838 patent specification compares certain properties of the prior art comparative liquid formulation with various diclofenac sodium gel preparations, including: transdermal flux, i.e., transport of the diclofenac sodium across skin (*id.*, 13:1-11; *id.*, col. 15-21, Examples 3-4); drying rates (*id.*, 21:38-23:29 & Fig. 11); and concentration of an "impurity A" (*id.*, 23:30-24:33).

c. Prosecution History of the '838 Patent Family

The '838 patent issued on August 28, 2012 from U.S. Patent Application No. 12/134,121 ("'121 application"), which was filed on June 5, 2008.

During four years of prosecution, the Examiner repeatedly rejected the claims of the '121 application as obvious over prior art disclosing diclofenac topical formulations with the same ingredients as now claimed. In response to each rejection, Applicants amended the claims, but still were not able to obtain allowance of any claims.

Then, on December 8, 2011, Applicants and the Examiner met. The summary of the interview indicates that Applicants represented that they would "provide evidence showing the unpredictability of the claimed combination." Ex. 6, '838 patent file history, Jan. 27, 2012 Interview, at ACT-PENN0003162. On December 23, 2011, Applicants amended the pending claims a fifth time to, *inter alia*, replace the transitional phrase "comprising" with "consisting essentially of" in the independent claims. *Id.*, Dec. 23, 2011 Amend., at ACT-PENN0003119-

29. Applicants' amendment was accompanied by two declarations from Nuvo employees. *Id.*, Desai & Vo Decls., at ACT-PENN0003145-52. Applicants argued that the declarations provided "evidence of unpredictability of adding penetration enhancers and their affect on flux" and that the "claimed [viscosity] values of 500-5000 centipoise clearly distinguishes" the prior art. *Id.*, Dec. 23, 2011 Amend., at ACT-PENN0003142, 3133. Following this final amendment, the Examiner allowed the claims without further comment. *Id.*, July 17, 2012 NOA, ACT-PENN0003248-52.

The Examiner allowed the claims only after Applicants: (i) added the "consisting essentially of" transition; (ii) modified the claimed ranges for virtually all ingredients; and (iii) added limitations requiring that the formulation have particular viscosity, drying, and/or flux. *See* Ex. 7, '838 claim 1 redline; Ex. 6, '838 file history, ACT-PENN0002883, 3258.

After allowance of the '121 application, Applicants submitted a series of continuation applications, four of which issued as the '613, '809, '913, and '591 patents, and most of which were allowed within less than one year of prosecution. *See* Ex. 4, '838 patent family tree (listing the following patents and applications allowed in less than one year: U.S. Pat. Nos. 8,871,809; 9,066,913; 9,101,591; 9,168,304; 9,168,305 & U.S. Pat. App. No. 14/705,649). The claims of these child patents are generally directed to diclofenac sodium topical formulations that contain different quantities of the same ingredients, but almost always within the ranges recited in the '838 patent claims. However, each child patent contains claims lacking at least one of the property-based limitations (e,g., viscosity, drying, flux) required by the claims of the '838 patent.

2. '450 Method of Treatment Patent Family

The five method of treatment patents shaded in blue in the family tree attached as Exhibit 11 are listed in the Orange Book in association with Pennsaid 2% w/w. Horizon has alleged that

Defendants infringe four of those patents, the ’450,’164, ’078, and ’110 patents, and has granted a covenant-not-to-sue with respect to the ’956 patent. All four of the asserted Orange Book-listed patents of the ’450 patent family currently at issue in this case are directed to methods of treating pain with diclofenac sodium in combination with at least one of: (i) an oral non-steroidal anti-inflammatory drug (NSAID); (ii) sunscreen; (iii) insect repellent; (iv) a second topical agent; or (v) a second prescription medication. Ex. 3, ’450 patent, claim 1; Ex. 8, ’164 patent, claim 1; Ex. 9, ’078 patent, claim 1; Ex. 10, ’110 patent, claim 12.

The earliest application in the ’450 patent family is a provisional application filed March 31, 2009. Ex. 11, ’450 patent family tree. As of March 2009, topical diclofenac sodium gels were already on the market, including Pennsaid® 1.5% w/w, which was sold by Nuvo’s predecessor, Dimethaid Health Care Ltd. Ex. 12, Dimethaid Monograph.

C. Level of Ordinary Skill

The parties’ contentions concerning the level of skill are not materially different. The person of ordinary skill in the art relevant to the patents-in-suit would have had an advanced degree, such as a Master’s or Ph.D., or an equivalent advanced degree in pharmaceutics, pharmacology, or a related discipline, as well as at least three years of experience in a pertinent field. Ex. 15, Oct. 15 Contentions, pp. 3-4; Michniak-Kohn Decl. ¶ 18.

III. LEGAL STANDARD

A. Claim Construction

The ultimate interpretation of a claim is a legal conclusion for the district court. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

In construing claims, courts must first examine the “intrinsic evidence,” which includes the language of the claims, the prosecution history, and the specification. *Phillips v. AWH Corp.*,

415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Id.* at 1312 (internal quotation marks and citations omitted). Although the specification "is the single best guide to the meaning of a disputed term," *id.* at 1315-16, "[l]imiting claims from the specification is generally not permitted absent a clear disclosure that the patentee intended the clams to be limited as shown." *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1334 (Fed. Cir. 2007). Courts also consider the prosecution history, which "demonstrat[es] how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

A court may also consider extrinsic evidence, such as expert and inventor testimony, dictionaries, and learned treatises. *Id.* at 1317-18. Extrinsic evidence can provide the court an understanding of the underlying technology or scientific principles and "the meaning of particular terminology to those of skill in the art of the invention." *Id.* at 1318.

B. Indefiniteness

Indefiniteness is a legal issue evaluated by a court as part of "its duty as the construer of patent claims." *In re Aoyama*, 656 F.3d 1293, 1299 (Fed. Cir. 2011); *see also Teva*, 135 S. Ct. at 836-37 (analyzing indefiniteness in context of claim construction). Because patent claims define the patentee's right to exclude, the claims must "particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. A claim is indefinite if, when "read in the light of the specification delineating the patent, and the prosecution history, [it] fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *See Nautilus, Inc. v. Biosig Instruments Inc.*, 572 U.S. _, 134 S. Ct.

2120, 2124 (2014). If one skilled in the art is unable to discern the bounds of the claim, the term should be held invalid as indefinite. *Id*.

IV. CONSTRUCTION OF DISPUTED TERMS

A. "Consisting Essentially Of"

Claim Term	Claims	Horizon's Proposed Construction	Defendants' Proposed Construction
"consisting essentially of"	'838 patent, claims 1-19, 21-24, 27-33, 35, 43, 46-52, 55-61[6] '591 patent: claims 12-15, 17, 24	Legal Issue – No construction needed in Markman phase; also, meaning cannot be ascertained in the absence of proper context	Comprising; if interpreted otherwise, the claims are invalid as indefinite and/or lacking adequate written description under 35 U.S.C. § 112.

Horizon's admitted inability to offer a construction without "proper context" highlights the term's indefiniteness. In order to sastify the definiteness requirement, the claim language must "inform with 'reasonable certainty,' those skilled in the art about the scope of the invention." *See Nautilus,* 134 S. Ct. at 2124. While "consisting essentially of" is generally "understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention,'" this presumes that such "basic and novel properties" are identifiable from the intrinsic record. *See AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239-40 (Fed. Cir. 2003). Here, the lack of any defined "basic

[6] On October 28, 2015, Horizon provided Defendants with covenants-not-to-sue ("CNS") on claims 1-48 and 62-69 of the '838 patent. Because the CNS's provided by Horizon were unduly restricted in scope, Defendants ask that the Court construe the disputed terms found in claims 1-48 and 62-69, which are necessary to resolve Defendans' declaratory judgment counterclaims of invalidity. Terms found only in claims 1-48 and 62-69 include: "said diclofenac sodium degrades by less than 0.04% over the course of 6 months," the drying rate limitation, "as determined by a franz cell procedure at finite or infinite dosing," and "hydroxypropylcellulose (HY119)." *See* Sections IV.C.2, IV.F-H, *supra*, at pages 24-26, 29-40. Regardless, "consisting essentially of" must be construed because Horizon continues to assert claims 49-52 and 55-61 of the '838 patent against Defendants.

and novel properties" in the intrinsic record, combined with Horizon's contention that "consisting essentially of" varies by "proper context" such that it excludes any ingredient inconvenient to defending the validity of its patents, leaves no recourse other than to hold this transitional phrase indefinite. Given the absence of any identifiable "basic and novel property," the claims fail to inform with "reasonable certainty, those skilled in the art about the scope of the invention" and are indefinite. *See Nautilus*, 134 S. Ct. at 2124; *see AK Steel*, 344 F.3d at 1239 (acknowledging "ambiguous nature of the phrase").[7]

1. The Claims Fail to Define the "Basic and Novel Properties" Needed for "Consisting Essentially Of"

Although three properties are recited in various claims of the '838 and '591 patents, these properties cannot be the "basic and novel properties of the invention" because that would render "consisting essentially of" superfluous. *See Merck & Co. v. Teva Pharms USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of a claim is preferred over one that does not do so."). Independent claims 1, 24, 49, and 62 of the '838 patent each require at least one of the following three properties: (1) "a viscosity of 500-5000 centipoise"; (2) "a greater drying rate"; and (3) "a transdermal flux of 1.5 times or greater . . . ." Ex. 2, '838 patent, 28:48, 51, 52; 29:59, 61-62; 30:67; 32:3, 7-8. If "consisting essentially of" limited the addition of unclaimed ingredients to only those that had no effect on these three properties, "consisting essentially of" would be improperly rendered redundant with these three

[7] To the extent the court holds the claim not indefinite, "consisting essentially of" should be construed as "comprising." *See* Ex. 13, M.P.E.P. § 2111.03 ("[a]bsent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising.'"). Here, the lack of any identified "basic and novel properties" leaves little choice other than construing "consisting essentially of" as "comprising" in this case. *Id.* If the transition "consisting essentially of" is construed as "comprising," the '838 patent claims encompass any formulation containing the listed ingredients and do not exclude any additional, unrecited ingredients or steps.

property limitations. *See Mangosoft, Inc. v. Oracle Corp.*, 525 F.3d 1327, 1330-31 (Fed. Cir. 2008) (rejecting construction that "ascribe[d] no meaning to the term 'local' not already implicit in the rest of the claim"). Accordingly, these three properties cannot be the "basic and novel properties of the invention" for purposes of the "consisting essentially of" transition.

Claim 49 of the '838 patent further confirms that the purported "basic and novel properties" cannot be the three properties recited in claim 1. Claim 49 requires the exact same ingredients in the same quantities as claim 1 – except that claim 49 does not recite "optionally glycerine." Ex. 2, '838 patent, 28:48, 30:60-67. Horizon contends that "[c]laim 49 . . . is further nonobvious via its inclusion of the 'consisting essentially of' transition phrase which excludes the glycerine disclosed by Sandborn." Ex. 16, Sept. 11 Contentions, p. 27; Ex. 14, Pls. Resp. Amneal's Invalidity Contentions, p. 28. It makes no sense that glycerine might impact the basic and novel properties of claim 49 while not affecting the three properties recited in the identical formulation of claim 1. Thus, the three properties recited in claim 1 cannot be the "basic and novel properties" of the invention.

2. The Specification Does Not Clarify the "Basic and Novel Properties"

The specification likewise fails to provide any clarity about the allegedly "basic and novel properties" of the claimed invention. The specification references "[s]tructure-permeabilty considerations in percutaneous absorption" known in the prior art, including solubility, size and charge, drug dissolution rate, spreading-ability, adhesion, ability to alter membrane permeability, the partition coefficient, pH of the vehicle and viscosity, but fails to identify how the claimed invention involves basic and novel variations on these "considerations." Ex. 2, '838 patent, 2:29-3:36. The specification further asserts that the "present invention satisfies" certain "needs," namely delivery of an active agent "in sufficient concentration to treat OA on a long term basis,

while reducing or minimizing the incidence of intolerable skin irritation . . . ." *Id.*, 4:9-18. However, the specification contains no disclosure of any skin irritation properties of the claimed formulation.[8] Thus, the specification fails to identify any "basic and novel properties" of the claimed invention.

3. Applicants Failed to Identify the "Basic and Novel Properties" During Prosecution

The prosecution history of the '838 patent sheds no light on any purportedly "basic and novel properties." Although the applicants repeatedly argued during prosecution that the "consisting essentially of" transition "limit[ed] the scope of the claims to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention," the applicants never affirmatively identified those characteristics or how additional ingredients would affect those characteristics. Ex. 6, '838 file history, at ACT-PENN003117-44. Instead, applicants made piecemeal arguments that the "consisting essentially of" transition excluded particular components of various prior art compositions, particularly, the dibasic ester of U.S. Pat. No. 5,350,769 ("Kasai"), and the ether alcohol and fatty alcohol ester of U.S. Pat. No. 5,374,661 ("Betlach"). Ex. 6, '838 file history, Dec. 23, 2011 Amend., at ACT-PENN0003134-35, 3142.

4. Horizon Incorrectly Seeks a Construction that Would Allow "Consisting Essentially Of" to Vary by Context

Horizon is wrong in arguing that no construction is needed because construction of "consisting essentially of" is a legal issue. Dkt. 72, pp. 4-5. First, the meaning of "consisting essentially of," including the identification of the purported "basic and novel properties of the

[8] The only reference to skin irritation outside the Background is a note in Example 8 that "skin irritation score will be documented" in clinical trials. Ex. 2, '838 patent, 28:12-15.

invention" is routinely handled in the *Markman* phase.[9] Second, Horizon's secondary position that the term's "meaning cannot be ascertained in the absence of proper context" confirms the need for clarification as to what, if any "basic and novel properties" are encompassed by Horizon's alleged "proper context." *Id.*

Horizon's position that the "meaning [of 'consisting essentially of'] cannot be ascertained in the absence of proper context" speaks volumes about the lack of identifiable "basic and novel properties." *Id.* In its contentions, Horizon argues that claims 1, 24, and 49 of the '838 patent and claim 12 of the '591 patent and their dependents "are . . . nonobvious via their inclusion of the 'consisting essentially of' transitional phrase," which allegedly gives Horizon a free pass over prior art that happens to include any ingredient other than those recited in the claims. (*See, e.g.*, Ex. 16, Sept. 11 Contentions, p. 34; Ex. 15, Oct. 15 Contentions, p. 17-18.) Thus, Horizon argues "consisting essentially" of:

- "excludes dibasic acid esters taught by Kasai to be required in the latter's formulation" (Ex. 16, Sept. 11 Contentions, p. 34);[10]
- "excludes *inter alia* the surfactant disclosed by Lu" (*id.*, p. 40, 71);

[9] *E.g.*, *Depuy Mitek, Inc. v. Arthrex, Inc.*, 297 Fed. App'x 995, 999-1000 (Fed. Cir. 2008) (noting district court judge defined four basic and novel properties); *Trs. of Boston Univ. v. Everlight Elecs. Co.*, 23 F. Supp.3d 50, 66 (D. Mass. 2014) (holding as a matter of claim construction that "ingredients may be added to the GaN 'first material' only if they do not materially affect the buffer layer's ability to grow near-intrinsic monocrystalline GaN films that can be controllably doped n-type or p-type"); *Gen. Elec. Co. v. Hoechst Celanese Corp.*, 698 F. Supp. 1181, 1187 (D. Del. 1988) ("In the present case, we hold that the determination of the basic and novel characteristics of the plastics patented by the '394 patent is a part of determining the scope of the claim."); *BASF Corp. v. Eastman Chem. Co.*, No. 95-746, 1998 U.S. Dist. Lexis 23054, at *29-30, 35-37 (D. Del. Mar. 24, 1998) (determining as a matter of claim interpretation that "'consisting essentially of' excludes the addition of any component B, a solubilizer" before separately assessing infringement).

[10] *See also* Ex. 14, Pls. Resp. Amneal's Invalidity Contentions, p. 34-35, 41, 43, 45, 47, 51-54, 60, 70, 72-73, 75-76, 85, 87, 90.

- "excludes PEG-7-glyceryl cocoate required by Sagitta" (*id.*, p. 42);
- "excludes PEGs, lipoidal thickening agents and emulsifiers which are required according to the teaching of Herschler" (*id.*, p. 44);
- "excludes other excipients taught by Baboota to be required in its formulations (e.g., PEGs, PVA and triethanolamine)" (*id.* at p. 46);
- "excludes other formulation components disclosed as being required in the Betlach formulations, e.g., ether alcohols, fatty alcohol esters and a neutralizing agent" (*id.*, p. 51);
- "excludes other formulation components disclosed as being required in the Kamishita formulations, e.g., a weak basic substance such as triethanolamine, which is 'one of the characteristic features of the [Kamishita] invention'" (*id.*, p. 52-53 (citation omitted), 65-66);
- "excludes inter alia the specific thickening bases which are required according to the teaching of Herschler II" (*id.*, p. 59);
- "excludes other formulation components disclosed as being required in the Naito formulations, e.g., isopropyl myristate to it as a sorbefacient" (*id.*, p. 76);
- "excludes other formulation components disclosed as being required in the Steiger formulations, e.g., a lipid forming the oily phase of the emulsion-gel, at least one non-ionic surfactant, and a basic agent to adjust the pH" (*id.*, p. 78);
- "excludes the polyacrylic acid polymer required by Dow" (*id.*, p. 81);
- "excludes other formulation components disclosed as being required in the Spann-Wade formulations, e.g., keratolytic agents" (Ex. 15, Oct. 15 Contentions, p. 19);
- "excludes dibasic acid esters taught by Ikeda to be required in the latter's formulation" (*id.*, p. 15); and
- "excludes other formulation components disclosed as being required in the Tomlinson formulations, e.g., a hydrophobic polymer." (*id.*, p. 18.)

Notably absent from Horizon's long list of exclusions is any affirmative statement of the basic and novel properties of the claimed invention. Horizon makes no effort to tie together its disparate list of excluded ingredients based on any common properties because there is no common thread.

Horizon's apparent belief that "consisting essentially of" operates as a negative limitation that excludes a variety of ingredients based on "proper context" (Dkt. 72, pp. 4-5)—without any mention of how those ingredients affect any property of the formulation, let alone a "basic and novel property"—runs counter to long-standing precedent. Courts evaluate whether additional unrecited elements are encompassed by claims having the "consisting essentially of" transition by assessing whether the unrecited element "materially affects the basic and novel properties of the claims." *See PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). For example, in *AK Steel Corp. v. Sollac & Ugine,* silicon in excess of 0.5% by weight was excluded from the claim where the specification indicated that such a quantity of silicon would not achieve the "principal object of the invention to form hot dip aluminum coated ferritic chromium alloy steels having enhanced wetting by the coating metal." 344 F.3d 1234, 1240 (Fed. Cir. 2003); *see also Oscar Mayer Foods Corp. v. Conagra, Inc.*, No. 94-1247, 1994 U.S. App. Lexis 36261, at *21 (Dec. 22, 1994) ("Any additional step which does not interfere with the [basic and novel property of] use of the lactate salt to inhibit growth of *C. bot.* . . . does not escape infringement.").

In sum, Horizon's vague, "context" dependent proposed ***nonconstruction*** injects unacceptable uncertainty, and deliberately so. Horizon hopes to exploit this uncertainty and treat the claims as a "nose of wax," using the "consisting essentially of" limitation to arbitrarily exclude whatever excipients necessary to dance around the prior art. *See Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1563 (Fed. Cir 1995) (Plager, J., concurring). But this misguided strategy has a fatal consequence for Horizon. It confirms that, based on this instrinsic

record, "consisting essentially of" lacks the "reasonable certainty" mandated by 35 U.S.C. § 112, ¶ 2 and is, therefore, indefinite.[11]

B. "Ethanol"

Claim Term	Claims	Horizon's Proposed Construction	Defendants' Proposed Construction
"ethanol"	'838 patent: claims 1-19, 21-24, 27-33, 35-43, 46-52, 55-69 '613 patent: claims 1-5, 9-19, 22-24 '809 patent: claims 2, 4-6, 10-15 '913 patent: claims 1-12 '591 patent: claims 1-3, 5, 6, 8-15, 19-25	A liquid containing between 92.3-93.8 % w/w or 94.9-96.0 % v/v C_2H_5OH	"Pure ethanol," i.e., C_2H_5OH, or "100% ethanol"; alternatively, this term is indefinite.

Defendants' proposed construction of "ethanol" to require "pure ethanol," i.e., C_2H_5OH, or 100% ethanol, is the only construction that comports with the plain language of the claims. As proposed by Defendants, "ethanol" means just what it says—"ethanol"—not a mixture of ethanol and water as Horizon incorrectly contends. By contrast, the "92.3-93.8% w/w" range in Horizon's construction appears nowhere in the claims or specification.

[11] Moreover, adopting a construction based on Horizon's laundry list of exclusions of various ingredients would render the claims invalid under 35 U.S.C. § 112, ¶ 1 for lack of adequate written description support. The specification of the '838 patent contains no mention of most of the ingredients Horizon now asserts are excluded by "consisting essentially of," let alone any explanation as to why the exclusion of such ingredients is necessary to maintain a basic and novel property of the invention. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

Defendants' construction of "ethanol" as "pure ethanol" is confirmed by the surrounding language of the claims. First, the claims recite neither a "92.3-93.8% w/w" range nor "USP." There is no legitimate reason for injecting into the claim the reference to "ethanol (USP)" from a single table in the patent specification. If the patentees had indended to claim "ethanol USP," then they should have drafted the claims to say so. Second, it makes little sense to construe the term "ethanol" as including water when many claims in the '838 patent family recite "water" as a separate element. *E.g.*, Ex. 2, '838 patent, claims 1, 24, 49, 62; Ex. 17, '613 patent, claims 1, 15; Ex. 5, '809 patent, claim 2; Ex. 18, '913 patent, claim 1; Ex. 19, '591 patent, claims 1 & 12. The claims do not qualify this separate "water" element as "additional water" or "supplemental water." *See Chip-Mender, Inc. v. Sherwin-Williams Co.*, 458 F. Supp. 2d 994, 1009 (N.D. Cal. 2006) ("[I]ncluding 'pigment and solvent' as part of the construction [of 'automotive paint composition'] would be redundant" where "pigment" and "solvent" were also recited in the claim.). Third, many claims expressly state that ethanol is "present" in the final formulation—not that the formulation is made from an ethanol/water mixture. *E.g.*, Ex. 2, '838 patent, claims 1, 62; Ex. 17, '613 patent, claims 15; Ex. 5, '809 patent, claim 2; Ex. 18, '913 patent, claim 1; Ex. 19, '591 patent, claim 1.

The '838 patent specification demonstrates that the patent claims' recitation of "ethanol" rather than an ethanol/water mixture was deliberate. The specification explains how one gel preparation may be made by "dissolving diclofenac sodium in an aqueous alcohol mixture (e.g., an ethanol/water mixture)." Ex. 2, '838 patent, 10:54-56. In Table 1, the patent lists "Ethanol (USP)," which Horizon contends is 92.3-93.8% ethanol and 6.2-7.7% water, as a material that may be used in the ***preparation*** of the example formulations. *Id.*, 12:18-19; Ex. 20, USP 29, Alcohol at ACT-PENN0014640; Ex. 21, Handbook at ACT-PENN0014606. However, rather

than claiming a method for ***preparing*** a formulation made with an "ethanol/water mixture" or "Ethanol (USP)" as ingredients, the claims require a final formulation having "ethanol ***present***" in specific percentages. The claims are unconcerned with how the ethanol got there, whether 100% ethanol or 50% ethanol in water. Instead, the claims merely require that "ethanol" is present at the claimed percentage. *See Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1369 (Fed. Cir. 2015) ("The statement in the specification that the concentration of the buffer 'may be' between 0.1 and 10 mg/ml is not limiting, because even if 'all of the embodiments discussed in the patent' included a specific limitation, it would not be 'proper to import from the patent's written description limitations that are not found in the claims themselves.'" (citation omitted)).

Extrinsic evidence confirms Defendants' construction. Like the patent, multiple references use the term "alcohol" to refer to a mixture of water and ethanol. Ex. 20, USP 29 at ACT-PENN0014640; Ex. 21, Handbook of Pharmaceutical Excipients at ACT-PENN0014606; Ex. 22, Hawley's Condensed Chemical Dictionary, p. 477; Ex. 23, Spectrum Chemical Webpages, HZNPENN_0035289, -297 ("Alcohol, 190 Proof, USP, is approximately 95% *Ethanol* and 5% water."), -298. These references demonstrate, however, that the claimed "ethanol" refers to the pure C_2H_5OH component of the mixture. Not only is Horizon's proposed contstruction contrary to the intrinsic record, but also it leads to a bizarre result. Horizon contends that Actavis's and Amneal's formulations, which respectively contain a specific concentration of ethanol, infringe three different claims requiring "ethanol present at" three specific yet different concentrations—25%, 25.5% and 26.5%. Ex. 2, '838 patent, claims 55-57. But it would be nonsensical for a formulation having ***one*** specific concentration of ethanol to simultaneously infringe claims requiring ethanol at ***three*** different concentrations.

C. Degradation Limitations

The degradation limitations, which rely on unspecified test parameters and an unknown "impurity A" for determining their scope, are indefinite under 35 U.S.C. § 112, ¶ 2. That is why Horizon attempts to distance itself from the clams as written, and instead presses for a construction that relies on an undisclosed surrogate for measuring degradation, USP Diclofenac Related Compound A RS. But Compound A is never mentioned in the patents, and there is certainly no basis for importing into the claims either Compound A or unclaimed test conditions, as Horizon now advocates in an effort to salvage validity. But it is not the Court's job to resuscitate invalid claims through the vehicle of claim construction.

1. "The Topical Formulation Produces Less Than 0.1% Impurity A After 6 Months at 25°C and 60% Humidity"

Claim Term	Claims	Horizon's Proposed Construction	Defendants' Proposed Construction
"the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity"	'913 patent, claim 4	Less than 1% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If impurity A is construed to mean USP Diclofenac Related Compound A RS, then the remainder of the term should be given its plain and ordinary meaning.

Horizon makes a transparent attempt to cure an otherwise indefinite claim when it asks the Court to rewrite claim 4's reference to unknown "impurity A" as "USP Diclofenac Related Compound A RS." The Court should decline this invitation—"impurity A" is the language the "patentee[s] claimed and what the public is entitled to rely on." *See Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010). The fact that "impurity A" is indefinite unless rewritten as "USP Diclofenac Related Compound A RS" is not grounds to

"redraft claims, whether to make them operable or to sustain their validity." *See Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004).

The claim's use of the lowercase "impurity A" indicates that the term refers to an unknown impurity, not the proper name of a known diclofenac intermediate like USP Diclofenac Related Compound A RS. Had the patentees meant to claim "USP Diclofenac Related Compound A RS," they would have said "USP Diclofenac Compound A RS" or its chemical name. They did not.

The specification does not make any mention of USP Diclofenac Related Compound A RS, let alone equate this known intermediate with "impurity A." Instead, the specification indicates that the patentees did not know what compound constitutes the so-called "impurity A" of claim 4. Example 6, which contains the patent's only discussion of "impurity A," reports:

> In this study, samples of the test compositions were placed into plastic screw cap bottles which were sealed and held at 25º C. at 60% humidity for 6 months. After the 6 month storage period, the samples were tested for impurities by high performance liquid chromatography (HPLC). The active agent, diclofenac sodium, was found to elute by HPLC with an elution time of about 11 minutes. It was found that upon 6 months of storage, an impurity, ***termed "impurity A"***, was seen to elute at about 6.6 minutes . . . .

Ex. 2, '838 patent, 23:48-57 (emphasis added). Thus, the specification references an unknown impurity that the patentees "termed" impurity A. The quotes around "impurity A" indicate that this is not the proper name of the impurity. Rather, the use of quotes is consistent with the patentees' practice of placing terms in quotes when providing unique definitions for those terms. *See* Ex. 2, '838 patent, 6:52-7:32. Finally, the specification discounts the need to identify "impurity A" because the amount found "would result in an exposure level well below limits that would require additional nonclinical testing[.]" *Id.*, 24:29-33. Accordingly, a person of ordinary skill reading the specification would understand that "impurity A" was an unknown impurity, not the known diclofenac intermediate, Compound A. Otherwise, the patentees would have simply

said USP Diclofenac Related Compound A RS instead of referring to some unidentified "impurity A." Michniak-Kohn Decl. ¶ 55.

The specification also fails to provide sufficient information about the high performance liquid chromatography ("HPLC") conditions used in Example 6 for a person of ordinary skill to determine if a particular composition contains the unidentified "impurity A." HPLC measures the time a compound takes to travel – or elute – through a chromatography column. *Id.* ¶ 52. The elution time for a particular compound will vary based on, *inter alia*, the packing material in the column, size of the column, mobile solvent, and temperature.[12] *Id.* ¶ 52. The patent specification states that "impurity A" "elut[ed] at about 6.6 minutes" using HPLC, but says nothing about the HPLC procedure used. Ex. 2, '838 patent, 23:30-24:33. As a result, the person of ordinary skill would have no way to replicate the procedure in the patent to determine if a particular formulation also contains an impurity that "elutes at 6.6 minutes" under the same conditions, much less to conclude that "impurity A" means Compound A.[13] Michniak-Kohn Decl. ¶ 52. As such, claim 4 is indefinite because the patent fails to provide sufficient information for a person of ordinary skill to determine the scope of the claim with reasonable certainty. *Id.*, ¶ 56.

Moreover, Horizon itself effectively conceded during prosecution of the '913 patent that "impurity A" is indefinite. During prosecution, the Examiner rejected application claim 41 (issued claim 4) as indefinite because:

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[12]For example, depending on HPLC conditions, the elution time for diclofenac sodium has been reported to vary between 0.9 minutes, ~5.5 minutes, and ~12.5 minutes. Ex. 24, Tehrani, Fig. 2; Ex. 25, Korodi, 981; Ex. 26, Roy, Fig. 1.

[13] Using various HPLC conditions, the elution time for USP Diclofenac Related Compound A RS (1-(2,6-dichlorophenyl)indolin-2-one) has been reported to vary between 5.1 minutes, 3.4 minutes, and ~7 minutes. Ex. 24, Tehrani, Fig. 2; Ex. 25, Korodi, 981; Ex. 26, Roy, Fig. 1.

> [A]pplicants' specification does not disclose the nature of "impurity A". As such, the metes and bounds of the claim is unclear because the nature of "impurity A" is undefined and uncharacterized.

Ex. 27, '913 file history, ACT-PENN0012863. Applicants then cancelled claim 41, thereby acquiescing in the Examiner's indefiniteness rejection. *Id.* at ACT-PENN0013407, 13409; *see Fantasy Sports Props., Inc. v. Sportsline.com, Inc.*, 287 F.3d 1108, 1115 (Fed. Cir. 2002). Shortly after the Examiner granted Horizon's request for prioritized examination under 37 C.F.R. § 1.102(e), on April 2, 2015, Horizon resubmitted application claim 41 (issued claim 4). Ex. 27, '913 file history, ACT-PENN0013421, 13428. Horizon made no effort to alert the Examiner of the prior indefiniteness rejection, let alone provide any explanation as to how the prior rejection was overcome. *Id.*, ACT-PENN0013430-31.[14] Then, on April 9, 2015, the Examiner allowed application claim 41 without any comment.

Horizon relies on little more than accident in its effort to define "impurity A" as USP Diclofenac Related Compound A RS. Dkt. 72, pp. 25-26 (citing USP 26; European Pharmacopoeia at 1686-87.) The patentees' arbitrary decision to "term" the unknown impurity of the '913 patent as "impurity A" is not grounds to graft the definition of a known manufacturing process intermediate that is coincidentally labeled "A" onto claim 4. This is particularly true here, where there is no mention of "USP Dicolfenac Related Compound A RS" anywhere in the intrinsic evidence.

Further, the extrinsic record confirms that a person of ordinary skill would not conclude that the '913 patent's unknown "impurity A" was USP Diclofenac Related Compoud A RS, or

[14] Accelerated examination subjected the Examiner to the objective of "complet[ing] the examination of [the] application within twelve months from the filing date of the application," which may be accomplished by mailing a notice of allowance. *See* Ex. 13, Manual of Patent Examining Procedure § 708.02(a), VII.F.

any other particular known compound for that matter. For example, European Pharmacopoeia reports five known impurities of diclofenac sodium, none of which can be eliminated as "impurity A." Ex. 28, European Pharmacopoeia at 1421-22; Michniak-Kohn Decl. ¶ 55. In addition, there could be any number of other impurities produced by the excipients of the topical formulation that might elute at 6.6 minutes under the unspecified HPLC conditions used in the experiments leading to Example 6 of the '838 patent. Given the limited information in the patent, there is no way a person of ordinary skill could determine with reasonable certainty that "impurity A" is USP Diclofenac Related Compound A RS rather than some other impurity. Michniak-Kohn Decl. ¶ 55.

Finally, should the Court accept Horizon's position that a person of ordinary skill would have understood unknown "impurity A" to mean USP Diclofenac Related Compound A RS, the remainder of Horizon's construction must nonetheless be rejected because it is inconsistent with the claim language. Claim 4 of the '913 patent requires that "the topical formulation ***produces less than 0.1% impurity A*** after 6 months at 25 °C and 60% humidity." Ex. 18, '913 patent, 30:22-24. By contrast, Horizon's proposed construction rewrites the claim to cover formulations in which "[l]ess than ***1%*** of Impurity A [is] ***present*** in a formulation sample after the sample was maintained at 25 °C and 60% humidity for 6 months," without regard to whether the impurity was ***produced*** during the 6 month period or was present as a manufacturing by-product.[15] Dkt. 72, pp. 25-26 (emphases added). Horizon's construction also expands claim 4's requirement that the formulation produce "less than 0.1%" of impurity A to cover a formulation producing "less than 1%." Therefore, if the Court concludes that the person of ordinary skill somehow would

[15] Compound A is 1-(2, 6-dicloropheny1) indolin-2-one, which is a known intermediate from which diclofenac is generally synthesized. Ex. 26, Roy, abstract.

divine that "impurity A" corresponds to USP Diclofenac Related Compound A RS, this term should otherwise be given its plain and ordinary meaning rather than wholly rewritten as Horizon requests.

2. "Said Diclofenac Sodium [the Formulation] Degrades by Less than 0.04% [1%] over the Course of 6 Months"

Claim Term	Claims	Horizon's Proposed Construction	Defendants' Proposed Construction
"said diclofenac sodium degrades by less than 0.04% over the course of 6 months"	'838 patent, claims 7, 66	Less than 0.04% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If construed, the term should be given its plain and ordinary meaning.
"the formulation degrades by less than 1% over 6 months"	'613 patent, claims 1, 5, 9-19, 22-24 '591 patent: claims 10, 11 and 19	Less than 1% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25ºC and 60% humidity for 6 months	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If construed, the term should be given its plain and ordinary meaning.

Several of the claims of the '838 and '613 patents require that either the diclofenac sodium itself or the overall formulation "degrades by less than" a particular percentage "over 6 months." Recognizing that these terms suffer from both a lack of adequate written description support and indefiniteness, Horizon not only asks the Court to read "Impurity A" into the claims and again equate the unknown impurity with USP Diclofenac Related Compound RS, but also to read temperature and humidity conditions into the claims. The Court should decline Horizon's improper attempt to redraft the claims to protect their validity. *See Chef Am.*, 358 F.3d at 1374.

Horizon's improper request that the Court import "impurity A" into these limitations appears to be fueled by the lack of written description support for a formulation that produces less than 1% of all impurities, as required by the '613 patent claims. Although Example 6

purports to describe "Stability Characteristics" of diclofenac sodium gel formulations, this Example reports measuring only one potential product of degradation ("impurity A").[16] Ex. 2, '838 patent, 23:30-24:33. However, the degradation of diclofenac sodium can lead to the formation of several additional impurities, known or unknown. *See, e.g.*, Ex. 28, European Pharmacopoeia at 1421-22. In addition, the '613 patent claims recite six excipients, each of which may have different degradation products. *See* Ex. 17, '613 patent, claims 1, 15 (requiring (i) DMSO, (ii) propylene glycol, (iii) ethanol, (iv) optionally glycerine, (v) water, and (vi) a thickening agent); Michniak-Kohn Decl. ¶ 51. Horizon should not be permitted to cure these fatal defects by rewriting these claim limitations to specify impurity A. When the patentees intended to claim impurity A, they expressly did so. *See* Ex. 18, '913 patent, claim 4.

Further, this term is indefinite because the claim language states only that the overall formulation "degrades by less than 1% over 6 months." The claims are silent as to the conditions under which the amount of degradation is to be measured, including temperature, exposure, humidity, and physical conditions (e.g., container type and material). Recognizing that a person of ordinary skill would not be able to determine with reasonable certainty the bounds of the claims without these parameters, Horizon asks the Court to read testing conditions into the claim in an effort to cure this ambiguity – i.e., "25ºC and 60% humidity." However, this is not what the claims say. *See Haemonetics*, 607 F.3d at 783.

Horizon's proposed construction is also contrary to the plain language of the claims because it would limit the claims to those formulations in which less than the specified amount

[16]If Horizon is allowed to to import "impurity A", these claims are indefinite for the same reasons discussed with respect to the "impurity A" limitation of the '913 patent. Specifically, the person of ordinary skill would not have known the identity of "impurity A," and therefore the degradation limitation of the'613 patent is indefinite for the same reasons as discussed in Section IV.C.1, *supra*, at 19.

of impurity A is "present" after 6 months, without regard to whether the impurity resulted from degradation during the 6-month period or was present as a manufacturing impurity.

The claims require that "the formulation degrades by less than 1%." To the extent the Court declines to find this limitation indefinite at the *Markman* stage, these terms should be given their plain and ordinary meaning rather than Horizon's improper construction. By contrast, Horizon's proposed construction improperly imports limitations into the claims, is inconsistent with the claim language, and should be rejected.

D. "Topical Diclofenac Preparation"

Claim Term	Claims	Horizon's Proposed Construction	Defendants' Proposed Construction
"topical diclofenac preparation"	'450 patent, claims 1-5, 7, 9-11, 14-20 '078 patent, claims 1, 2, 5, 9, 11, 14 '164 patent, claims 1, 2, 5-8 '110 patent: claims 1-28	A solution or gel formulation for transdermal administration of diclofenac or its pharmaceutically acceptable salts thereof or its free acid form as described in the claims	A preparation containing diclofenac, or pharmaceutically acceptable salts thereof or its free acid form, that can be applied to the skin or mucosa.

The parties dispute whether a "topical diclofenac preparation" is limited to a "solution or gel" (Horizon's position) or includes any preparation that can be applied to the skin or mucosa (Defendants' position).

Defendants' construction accords with the claim language, which broadly recites "preparation" rather than "solution or gel." The specification of the '450 patent family uses the phrase "topical diclofenac solution or gel" (*see e.g.*, Ex. 3, '450 patent, 8:61-62), and thus the patentees would have included the limiting terms "solution or gel" in the claims had this been the intended scope. *See Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed.

Cir. 2008) (noting that patentees use different terms to connote different meanings). Instead, the patentees claimed the invention more broadly, and they should be held to that decision. Further, Defendants' construction is consistent with the patentees' express definition of "topical formulation" as a "formulation that can be applied to the skin or mucosa." Ex. 3, '450 patent, 10:41-45 (incorporating by reference Nuvo's WO 2008/049020); Ex. 29, WO 2008/049020, [0047].

By contrast, Horizon asks the Court to arbitrarily limit the term "preparation" to a solution or gel in an effort to overcome prior art. This is contrary to the plain language of the claims as understood by a person of ordinary skill. Dictionaries, treatises and the U.S. Food and Drug Administration's industry guidance all establish that a person of ordinary skill would understand a topical "preparation" includes not only solutions and gels, but also creams, lotions, emulsions, and other topical formulations. Dictionary.com; Ex. 30, FDA Guidance.

E. "Informing" Limitations

Claim Term	Claims	Horizon's Proposed Construction	Defendants' Proposed Construction
"the patient being informed to"	'110 patent: claims 1-9, 24	The patient is instructed by a medical care worker, either orally, by published material or by demonstration, to perform the steps of the method	The patient is instructed to perform the steps of the method. Alternatively, this term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.
"the patient carrying-out steps i-iii as informed"	'110 patent: claims 1-9, 24	The patient performs each of steps i-iii as instructed by a medical care worker, either orally, by published material or by demonstration	The patient performs each of steps i-iii as instructed. Alternatively, this term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.

"providing information"	'110 patent: claims 10-11, 18-19, 26	A medical care worker providing instructions, either orally, by published material or by demonstration	Providing instructions. Alternatively, this term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.
"informing the patient to"	'110 patent: claims 12-13, 20-21, 27-28	The patient is instructed by a medical care worker, either orally, by published material or by demonstration, to perform the steps of the method	The patient is instructed to perform the steps of the method. Alternatively, this term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.

The parties dispute one aspect of the "informing" limitations: whether the patient must be instructed "by a medical care worker" (Horizon's position) or may be instructed by any means (Defendants' position).

Defendants' construction accords with the claim language, which broadly recites "the patient being informed to," "the patient carrying-out steps i-iii as informed," "providing information," and "informing the patient to." The parties agree that the "informing" limitations should be construed as "instructing." Nothing in the claim language limits the manner in which the patient is instructed or requires that the instruction be "by a medical care worker." Further, Defendants' construction is consistent with patentees' express definition of "informing" as:

> [R]eferring to or providing, published material including in electronic form, for example, providing published material to a user; or presenting information orally, for example, by presentation at a seminar, conference, or other educational presentation, by conversation between a pharmaceutical sales representative and a medical care worker, or by conversation between a medical care worker and a patient; or demonstrating the intended information to a user for the purpose of comprehension.

Ex. 10, '110 patent, 15:21-29. While this definition mentions medical care workers, it does not state that instruction by a medical care worker is the only means of informing the patient.

Moreover, nothing in the file history of the '110 patent indicates that Horizon intended to limit "informing" to instruction "by a medical care worker."

By contrast, Horizon asks the Court to arbitrarily limit the "informing" limitations to instruction by a medical care worker. Horizon's proposed constructions improperly import limitations into the claims, are inconsistent with the claim language, and should be rejected.

F. Drying Rate Limitations

1. "A Greater Drying Rate"

Claim Term	Claims	Horizon's Proposed Construction	Defendants' Proposed Construction
"a greater drying rate"	'838 patent: claims 1-19, 21-24, 27-33, 35-43, 46-48, 62-69	Wherein a lesser amount (wt) of the claimed formulation remains relative to the amount (wt) of the comparative liquid formulation after 100 mg of both formulations are spread over 10 cm^2 area and exposed to ambient conditions over a 24 hour period	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If construed, "a greater drying rate" requires a lesser amount (wt) of the claimed formulation remains relative to the amount (wt) of the comparative liquid formulation after 100 mg of both formulations are spread over 10 cm^2 area and exposed to ambient conditions over a time period

a. "A Greater Drying Rate" Is Indefinite

Horizon asks the Court to read a whole paragraph worth of testing procedures into "a greater drying rate" in an effort to clarify the term sufficiently to bring it in compliance with definiteness requirement of pre-AIA § 112 ¶ 2. However, claim construction is not an opportunity to "redraft claims, whether to make them operable or to sustain their validity." *See Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004).

The term "a greater drying rate" fails to inform those skilled in the art of the scope of the invention, and therefore is indefinite. *Nautilus*, 134 S. Ct. at 2124. Under *Nautilus*, it is not

sufficient that someone skilled in the art ***could*** arrive at a method of practicing the invention. *Dow Chem. Co. v. Nova Chems. Corp.*, No. 2014-1431, 2015 U.S. App. Lexis 15191, at *28–29 (Fed. Cir. Aug. 28, 2015). Rather, the intrinsic evidence must provide guidance as to the correct method, so those of skill in the art know the "objective boundaries" of the invention. *Id*. at *20. Here, the intrinsic evidence fails to indicate the proper method for assessing "a greater drying rate," leaving one skilled in the art to guess how and when such a measurement should be made. The term, thus, creates uncertainty as to the objective boundaries of the claims and is indefinite. *See id.* at *28-29; Michniak-Kohn Decl. ¶ 30.

i. The Claims Fail to Specify which of Two Disclosed "Drying Rate" Methods to Use

The term "a greater drying rate," is indefinite because the claims do not specify the method for assessing drying rate, and the measured drying rate depends upon the method selected. *Dow Chem. Co.*, 2015 U.S. App. Lexis 15191, at *29-31.

The appropriate method is unclear because the intrinsic evidence describes two possible methods for assessing drying, but the claims do not state which to use. First, the specification describes an *in vivo* test in which "equal amounts of . . . two products are tested on opposite limbs" and the dryness of each is observed after thirty minutes. Ex. 2, '838 patent, 10:14-21. Second, the specification describes an *in vitro* test in which "equal weight amounts (100 mg)" of two formulations are "measured on to plastic weigh dishes and spread over a 10 cm^2 area, and then left exposed to ambient conditions." *Id.*, 21:47-51; *see also id.*, 10:22-30.

The patent itself indicates that the choice of the *in vivo* or *in vitro* method would likely affect whether a particular diclofenac sodium gel exhibited a "greater drying rate" than the comparative liquid formulation. The patent reports that "within" 30 minutes using the *in vivo* test, the "compositions of the invention are almost completely dry whereas a significant amount

of the previously described liquid formulation remains." *Id.*, 10:16-21. By contrast, no meaningful difference in drying was observed after 30 minutes in the *in vitro* test—the weight remaining for the gels was 92.7%, 93.3% and 100% versus 95.6% for the comparative liquid formulation. *Id.*, Fig. 11, 23:1-29; Michniak-Kohn Decl. ¶ 26. Moreover, at least one gel—F971—purportedly dried ***less*** than the comparative liquid formulation after 30 minutes. *Id.* The *in vivo* test's "completely dry" results for the gel contrast sharply with the *in vitro* test's 92.7-100% remaining for the gels.

Given that whether a formulation has a "greater drying rate" will vary depending on which of the two possible test methods is used, the "greater drying rate" limitation is indefinite because a person of ordinary skill cannot determine with reasonable certainty whether the limitation is met. *See Dow Chem. Co.*, 2015 U.S. App. Lexis 15191, at *29-31; Michniak-Kohn Decl. ¶ 26. Similarly, in *Dow*, the Federal Circuit held claims indefinite where multiple methods existed for determining whether the "slope of strain hardening coefficient is greater than or equal to 1.3" and the "method chosen . . . could affect whether or not a given product infringes." *Dow Chem. Co.*, 2015 U.S. App. Lexis 15191, at *27-28. Just like the greater "slope of strain hardening" in *Dow*, the "greater drying rate" limitation is indefinite because the intrinsic evidence fails to specify "which method should be used." *See id.* at *28-29.

ii. Even if "A Greater Drying Rate" Incorporates Example 5, the Failure to Specify Time is Fatal

Even if it were clear that the claimed "drying rate" should be determined by the *in vitro* method disclosed in Example 5 as Horizon contends (Dkt. 72, pp. 5-7), "a greater drying rate" is indefinite because a person of ordinary skill would not know ***when*** to measure drying rate for the comparison. Michniak-Kohn Decl. ¶ 27. Table 12 of the '838 patent illustrates that when using the Example 5 *in vitro* method, the time at which the remaining percentage is measured can

determine whether or not a particular formulation is covered by the claims. Ex. 2, '838 patent, 22:50–23:27. As shown in the highlighted excerpt of Table 12 below, the gel labeled F971, which contains ingredients in the percentage ranges required by claim 24 of the '838 patent, allegedly displayed ***less*** drying with the *in vitro* test than the comparative liquid formulation from 0 to 1 hours (green).[17] Michniak-Kohn Decl. ¶ 29. However, beginning at the 4-hour time point, the "% Remaining" for F971 allegedly dipped below that of the comparative liquid formulation, i.e., F971 displayed ***greater*** drying (yellow). *Id.*, ¶ 29.

	% Remaining			
Time (hr)	Comparative	F14/2 gel 2.5%	F14/2 gel 4.0%	F971
0.000	100	100	100	100
0.083	98.1	93	92.6	100.3
0.167	96.7	92.9	91.8	100.3
0.333	95.7	92.7	93	100.2
0.500	95.6	92.7	93.3	100
0.750	95.5	92.1	92.3	99.8
1.000	95.9	92	91.8	99.7
4.000	93	71	70.7	86.8
24.000	88.7	32.4	23.5	58.8

Ex. 2, '838 patent, 23:18-27. Thus, Figure 12 demonstrates that even if the Example 5 *in vitro* method were read into the claims, a person of ordinary skill could not determine with reasonable certainty whether a particular formulation infringes because whether formulations having the claimed composition display "a greater drying rate" under Example 5 depends on when they are compared. Thus, even if the Example 5 *in vitro* method is incorporated into the claims, the choice of time can and will produce different results and affect whether or not a given product

[17] The *in vitro* drying method and data reported in columns 21-23 suffers from numerous flaws, including: (i) the lack of replicates in testing; (ii) failure to report the shape of the "weigh dishes" used; (iii) lack of humidity, temperature and airflow information for the "ambient conditions," and (iv) inexplicably large time intervals (e.g., no reported data between 4 and 24 hours). Michniak-Kohn Decl. ¶ 29 n.1.

satisfies "a greater drying rate," rendering the limitation indefinite. *Dow Chem. Co.*, 2015 U.S. App. Lexis 15191, at *27–29.

Extrinsic evidence sheds light on the complexities in drying that underlie the results shown in Figure 12. A person of ordinary skill would understand that the drying rate of a substance will frequently change at the point when the film of moisture on the substance becomes partially or completely dry. Ex. 31, Lachman, p. 51; Michniak-Kohn Decl. ¶ 21. Prior to this point, drying is driven by humidity and surface area. After this point, the applicable "heat and mass transfer equations become more complex" as "the rate of drying is controlled by the rate of diffusion of moisture from the interior of the material." Ex. 31, Lachman, p. 51. Thus, the rate of drying may vary based on the timing of the film's drying, a factor that may vary between a gel and a liquid formulation. Michniak-Kohn Decl. ¶ 21.

b. Horizon's Construction Improperly Reads Limitations into the Claims

Alternatively, if the Court accepts Horizon's position that "a greater drying rate" somehow implicitly incorporates the *in vitro* method of Example 5, the Court should adopt Defendants' alternate construction, which correctly adheres to the actual language of the limitation. Ex. 2, '838 patent, 28:49-51; *see also id.*,10:27-30, 21:39–22:49.

By contrast, Horizon improperly attempts to cure indefiniteness by arbitrarily reading a 24-hour time point limitation into "a greater drying rate." Dkt. 72, p. 5. A 24-hour limitation cannot be imported into the claims "absent a clear indication in the intrinsic record that the patentee[s] intended the claims to be so limited." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004). There is no such "clear indication" here given that Example 5 recites nine discrete time points for testing and ascribes no special significance to the 24-hour time point. Moreover, the patentees knew how to claim a specific time point when that was the

intent. For example, dependent claim 5's addition of a specific time point for measuring the residue resulting from "said drying rate" indicates that independent claim 1 is not limited to any particular time point. *See, e.g.*, *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1345 (Fed. Cir. 2008) (holding district court erred "in relying on the dependent claims" to import a temporal restriction into independent claims – "contrary to basic claim construction principles").

2. "Said Drying Rate Results in a Residue of at Most 50% of a Starting Amount after 24 Hours"

Claim Term	Claims	Horizon's Proposed Construction (annotated)	Defendants' Proposed Construction
"said drying rate results in a residue of at most 50% of a starting amount after 24 hours"	'838 patent, claim 5	[1] Wherein a lesser amount (wt) of the claimed formulation remains relative to the amount (wt) of the comparative liquid formulation after 100 mg of both formulations are spread over a 10 cm2 area and exposed to ambient conditions over the same time period, and [2] wherein the amount of the claimed formulation remaining after 24 hours of the exposure is no more than 50 wt.% of the starting amount (wt)	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If construed, the term should be given its plain and ordinary meaning.

Claim 5 is not directed to the relative drying rates of the claimed and comparative formulations, and thus the fatal indefiniteness of claim 1 is carried over into claim 5. *See Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1250, n.2 (Fed. Cir. 2008). Instead, claim 5 is directed to the amount of residue that the claimed formulation's "said drying rate" leaves after 24 hours. If the Court is nonetheless inclined to construe this term despite the invalidity of claim 5, Defendants' proposed "plain and ordinary" meaning construction is the correct one.

Claim 5 means what it says; there is no special meaning associated with the claim language. Horizon's construction, on the other hand, injects limitations that are simply not there. The underlined portion of Horizon's construction improperly grafts Horizon's proposed construction of the "greater drying rate" limitation of claim 1 onto the "residue" that results from "said drying rate" limitation of claim 5. Further compounding the error, instead of the "***over a 24 hour period***" that Horizon advocates for the "greater drying rate" in claim 1, Horizon attempts to inject an "***over the same time period***" modifier in claim 5. There is simply no legitimate basis for repeating in claim 5 the "greater drying rate" limitation of claim 1.

G. "As Determined by a Franz Cell Procedure at Finite or Infinite Dosing"

Claim Term	Claims	Horizon's Proposed Construction	Defendants' Proposed Construction
"as determined by a Franz cell procedure at finite or infinite dosing"	'838 patent, claims 1-19, 21-24, 27-33, 35-43, 46-48, 62-69	The Franz cell procedure as described in the '838 patent at col. 13, ll. 1-32 (including the Franz article cited therein)	This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed.

1. The Claims Fail to Specify Parameters for "a Franz Cell Procedure," Rendering the Term Indefinite

Only formulations having, among other claimed features, a "transdermal flux of 1.5 times or greater ***as determined by a Franz cell procedure at finite or infinite dosing***" infringe independent claims 1, 24, and 62 of the '838 patent, and their dependents. Ex. 2, '838 patent, 28:52-54, 29:62-63, 32:8-9 (emphasis added). However, the claims are silent on the necessary details of the "Franz cell procedure" that a person of ordinary skill would require to determine with reasonable certainty whether a particular formulation produces the claimed flux—including time, cell type, membrane type, dosing amount, and pH of the receptor fluid. Michniak-Kohn Decl. ¶ 37. Instead of specifying these parameters, the claims vaguely reference "***a*** Franz cell procedure," leaving the person of ordinary skill to guess at which of the many available Franz

cell options should be employed to assess infringement. *Id.*, ¶ 37; Ex. 32, Brain at HZNPENN_0038185-97 (describing various Franz cell procedures). As such, claims requiring a particular flux "as determined by a Franz cell procedure at finite or infinite dosing" are invalid due to indefiniteness under 35 U.S.C. § 112, ¶ 2. Michniak-Kohn Decl. ¶ 43.

Recognizing the claims' indefiniteness, Horizon again asks the Court to transplant the specification into the claims in an effort to cure the fatal lack of specificity in "a Franz cell procedure." However, necessary parameters for a Franz cell procedure, such as time, cell type, membrane type, dosing amount, and pH of receptor fluid, cannot be imported into independent claims 1, 24, and 62. *See In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1372 (Fed. Cir. 2007) (holding process need not be performed at 42 ºC where "the asserted 42 ºC 'limitation' was only an example from the specification"); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1348 (Fed. Cir. 2002) (holding terms not "limited to the[ ] precise conditions" of the specification). Indeed, when the patentees intended to claim details of "a" Franz cell procedure, they did so. Dependent claims 18 and 33 recite a dose of "10 mg per Franz cell and [that] the cell has an area of 0.5 cm^2." *See* Ex. 2, 838 patent.

2. The Patent's Failure to Specify Time Renders "a Franz Cell Procedure" Indefinite

Regardless of whether the Court permits Horizon to import the Franz cell procedure at column 13, lines 1-32, into the claims, the claims are still indefinite due to the lack of a timeframe for measurement. Neither the claims nor the specification (including the cited Franz cell article) define a timeframe for assessing whether the claimed formulation meets the required flux values, leaving the person of ordinary skill to guess when flux should be evaluated. *Storm Products, Inc. v. Ebonite Int'l, Inc.*, 638 F. Supp. 2d 1307, 1313 (D. Utah 2009) *aff'd sub nom. Storm Products v. Ebonite Int'l, Inc.*, 374 F. App'x 983 (Fed. Cir. 2010) (holding "a larger

number of bowlers" incapable of construction where "large" was not tied to a limited time and space) ; Michniak-Kohn Decl. ¶ 41.

The addition of time parameters in certain dependent claims of the '838 patent highlights the deficiencies of independent claims 1, 24, and 62. *See, e.g.*, *Signal IP v. Am. Honda Motor Co.*, No. 14-2454, 2015 U.S. Dist. Lexis 137339, at *106-07 & n.15 (C.D. Cal. Apr. 17, 2015) (holding independent claims indefinite while finding deficiency cured in dependents "recit[ing] a specific parameter"). For example, dependent claims 15 and 30 set forth specific timeframes at which infringement should be assessed. Michniak-Kohn Decl. ¶ 36.

Further, the '838 specification demonstrates why the absence of a timeframe prevents a person of ordinary skill from determining with reasonable certainty whether a given formulation satisfies the claims. Figure 7 of the '838 patent shows that at 18, 24, and 52 hours, the flux of the gel formulation was more than 1.5 times greater than an equivalent dose of the comparative liquid formulation. By contrast, the gel formulation's flux was less than 1.5 times greater at 5 and (possibly) 7 hours, as well as at 65 hours. Ex. 2, '838 patent, Fig. 7, 18:1-19:17. Thus, whether the flux is measured at 5 hours versus 18 hours, for example, makes a material difference in whether infringement is found. Accordingly, the claim's failure to specify the time at which the flux should be measured renders "a Franz cell procedure" indefinite. *See Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1339 (Fed. Cir. 2003) (holding claims indefinite where infringement depended on which of four sample preparation methods was used and the patent failed to give guidance on which method to use); Michniak-Kohn Decl. ¶¶ 41, 43.

The Examiner's statements during prosecution further underscore the need for timeframe to assess infringement "by a Franz cell procedure." During prosecution, the Examiner noted that a person of ordinary skill would be able to "calculate the flux values for any Franz cell, once

knowing the size of the Franz cell (area), the amount of diclofenac added to the cell and the measurement period (time)." Ex. 6, '838 file history, Nov. 25, 2011 Office Action, at ACT-PENN0003098. Thus, the Examiner recognized that the timeframe of measurement is a critical parameter for testing via a Franz cell.

Applicants likewise presented evidence during prosecution showing that relative flux measurements may vary based on the timeframe at which Franz cell data is measured. Figure 1 of Dr. Desai's declaration shows that the relative flux (accumulated dose) of the four sample gels differed, depending on the time at which the accumulated dose was measured. *Id.*, at ACT-PENN0003147, ¶ 12. For example, formulation Pgel111 had the largest accumulated dose after 8 hours but had a smaller accumulated dose than formulation Pgel112 after 20 hours. *Id.* at Fig. 1. The existence of these relative differences in accumulated dose at different times simply underscores the need for a timeframe for flux measurements in order for a person of ordinary skill to have a means to determine infringement with the requisite "reasonable certainty."

H. "Hydroxypropylcellulose (HY119)"

Claim Term	Claims	Horizon's Proposed Construction	Defendants' Proposed Construction
"hydroxypropyl-cellulose (HY119)"	'838 patent, claim 63	hydroxypropyl cellulose, 150-400 centipoise	The specific hydroxypropylcellulose obtained from Spectrum under vendor number HY119 and CAS 9004-64-2.

The claims, intrinsic record, and extrinsic evidence all indicate that "hydroxypropylcellulose (HY119)" is a specific brand of hydroxypropylcellulose and refers to the "specific hydroxypropylcellulose obtained from Spectrum under vendor number HY119 and CAS 9004-64-2."

The patentees explicitly limited Claim 63 to "hydroxypropyl-cellulose (HY119)," in contrast to other claims that more broadly recite the use of "hydroxypropylcellulose." *Compare* Ex. 2, '838 patent, 32:23-24 (claim 63) *with, e.g., id.*, 28:47 (claim 1). This creates a presumption that different terms have different meanings, and that the term "HY119" is not superfluous. *See Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1254-55 (Fed. Cir. 2011) (refusing to "read[ ] a split limitation or incomplete circle limitation into the term 'spring metal adaptor'" where other claims expressly recited a "split circular spring metal adaptor" because doing so "would render these additional modifiers superfluous").

Defendants' construction gives meaning to the term "HY119" and is consistent with the specification of the '838 patent, which provides that the Source, Vendor #, and CAS for the term "HY119" are Spectrum, HY119, and CAS 9004-64-2, respectively. Ex. 2, '838 patent, 12:33-35. The specification also reports that of the "[s]everal thickeners [that] were tested," three specific types of hydroxypropylcellulose—HY117, HY119, and HY121—were "most aesthetically pleasing." *Id.*, 16:26-30. The specification also provides data for several formulations containing HY119. *Id.*, col. 17, Tables 5 & 7, col. 19, Tables 8-10, col. 21-23, Table 11-12.

Further, Defendants' construction is confirmed by extrinsic evidence: the source (Spectrum), vendor # (HY119) and CAS # (9004-64-2) point to Spectrum's Material Safety Data Sheet for HY119. Ex. 33, Spectrum, at ACT-PENN0014534.

By contrast, Horizon's construction of "HY119" as "hydroxypropylcellulose, 150-400 cps" improperly seeks to expand the scope of claim 63 to cover any vendor's hydroxypropylcellulose having a particular range of viscosity. This is contrary to the plain language of claim 63, which defines the required hydroxypropylcellulose by a vendor abbreviation and not with regard to viscosity. Ex. 2, '838 patent, 12:33. Had the patentees

wished to claim hydroxypropylcellulose having a viscosity of 150-400 cps, claim 63 could have been drafted to recite "hydroxypropylcellulose, 150-400 cps." But that is not what the claim recites. *See Haemonetics*, 607 F.3d at 783.

V. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court enter an order construing the disputed terms consistent with Defendants' proposed constructions.

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